



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 56, 145, 146, and 147

[Docket No. APHIS-2014-0101]

RIN 0579-AE16

National Poultry Improvement Plan and Auxiliary Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the National Poultry Improvement Plan (NPIP), its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza. Specifically, we are clarifying who may participate in the NPIP, amending participation requirements, amending definitions for poultry and breeding stock, amending the approval process for new diagnostic tests, and amending slaughter plant inspection and laboratory inspection and testing requirements. These changes will align the regulations with international standards and make them more transparent to Animal and Plant Health Inspection Service stakeholders and the general public. The changes in this final rule were voted on and approved by the voting delegates at the Plan's 2014 National Plan Conference.

DATES: Effective [Insert date 30 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: Dr. Denise Brinson, DVM, Director, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094-5104; (770) 922-3496.

## SUPPLEMENTARY INFORMATION:

### Background

The National Poultry Improvement Plan (NPIP, also referred to below as "the Plan") is a cooperative Federal-State-industry mechanism for controlling certain poultry diseases. The Plan consists of a variety of programs intended to prevent and control poultry diseases. Participation in all Plan programs is voluntary, but breeding flocks, hatcheries, and dealers must first qualify as "U.S. Pullorum-Typhoid Clean" as a condition for participating in the other Plan programs.

The Plan identifies States, flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan's various programs. As a result, customers can buy poultry that has tested clean of certain diseases or that has been produced under disease-prevention conditions.

The regulations in 9 CFR parts 145, 146, and 147 (referred to below as the regulations) contain the provisions of the Plan. The Animal and Plant Health Inspection Service (APHIS, also referred to as "the Service") of the U.S. Department of Agriculture (also referred to as "the Department") amends these provisions from time to time to incorporate new scientific information and technologies within the Plan. In addition, the regulations in 9 CFR part 56 set out conditions for the payment of indemnity for costs associated with poultry that are infected with or exposed to H5/H7 low pathogenic avian influenza and provisions for a cooperative control program for the disease.

On March 24, 2016, we published in the Federal Register (81 FR 15652-15660, Docket No. APHIS-2014-0101) a proposal<sup>1</sup> to amend the regulations by clarifying who may participate in the NPIP and amending participation requirements. In addition, we proposed to amend

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<sup>1</sup> To view the proposed rule and the comment we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2014-0101>.

definitions of poultry and breeding stock, amend the approval process for new diagnostic tests, and amend slaughter plant inspection and laboratory inspection and testing requirements.

We solicited comments concerning our proposal for 60 days ending May 23, 2016. We received one comment by that date. It was from an individual. The issues raised by the commenter are discussed below.

In the March 2016 proposed rule, we proposed to amend the definition of breeding flock in § 56.1 to remove the word “chicks” and replace it with the word “progeny.” The commenter objected to this change, suggesting that many people would not know the meaning of the latter term and would find it confusing.

We are not making any changes to the final rule in response to this comment. As stated in the March 2016 proposed rule, the term “progeny” is more accurate than “chicks” in this context because it is more inclusive of both chicken and turkey flocks. Young turkeys are known as poults rather than chicks. In addition, as we noted in the proposed rule, the change in terminology also makes our definition of breeding flock in § 56.1 consistent with our definition of multiplier breeding flock in § 145.1.

The March 2016 proposed rule included a minor change to § 145.12, which contains requirements for the retention and examination of records for all flocks maintained primarily for hatching eggs. We proposed to specify, in paragraph (b) of that section, that records for all breeder flock hatcheries must be made available for annual examination by a State inspector. Historically, testing records were retained at the hatchery, which allowed for examination of the records during annual inspections, but that is no longer the case. Many commercial hatcheries now keep testing records at the corporate office or another site. Our proposed amendment to § 145.12 was intended to reflect this change in recordkeeping practices in the industry and also

to allow flexibility in the regulations regarding who may make the records available to the State inspector.

The commenter objected to this proposed change, stating that the records should be kept at the hatchery with the flocks so that taxpayers do not have to incur additional costs due to the need for inspectors to travel to different locations.

We do not agree with this comment. As noted above, we are amending the regulations to reflect current practices in the industry. By allowing hatcheries the discretion to maintain records where they would most readily be accessible when needed, we are relieving a regulatory burden. The commenter provides no evidence to support the claim that having the records kept at sites other than the hatcheries will result in additional costs to taxpayers.

The commenter also stated that the proposed rule would have the effect of loosening testing standards, thereby increasing the risk of the spread of disease.

We did not propose to loosen existing testing standards, as the commenter claims. We proposed instead to make some editorial changes to § 145.14(b) to remove references to tests that are no longer being used, update terminology that is no longer current, and otherwise clarify the testing requirements in that section.

Finally, the commenter objected to our proposed changes to the slaughter plant inspection requirements in § 146.11.

We will not be making any changes to the final rule in response to this comment. The commenter did not offer a rationale for opposing the proposed amendments to § 146.11, which were intended to clarify our slaughter plant inspection requirements and remove language that conflicted with requirements set out elsewhere in part 146.

#### Miscellaneous

In this final rule, we are making one minor editorial change to correct an error in the regulatory text of the proposed rule.

Part 146 of the regulations contains the NPIP provisions for commercial poultry. Currently, the only disease addressed in this part is H5/H7 low pathogenic avian influenza; under part 146, table-egg layer flocks, meat-type chicken slaughter plants, meat-type turkey slaughter plants, and certain types of game birds and waterfowl may participate in U.S. H5/H7 Avian Influenza Monitored classifications.

Section 146.11 sets out the audit process for participating slaughter plants. Paragraph (b) states that flocks slaughtered at a slaughter plant will be considered to be not conforming to the required protocol of the classifications if there are no test results available, if the flock was not tested within 21 days before slaughter, or if the test results for the flocks were not returned before slaughter. We intended to amend paragraph (b) to state that “a flock will be considered to be conforming to protocol if it meets the requirements as described in §§ 146.33(a), 146.43(a), 146.53(a).” However, we inadvertently referred to § 145.33(a) instead of § 146.33(a). In this final rule, we are correcting that error.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the change discussed in this document.

#### Executive Order 12866 and Regulatory Flexibility Act

This final rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document

for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

We are amending the NPIP, its auxiliary provisions, and the indemnity regulations for the control of H5 and H7 low pathogenic avian influenza to align the regulations with international standards and make them more transparent to stakeholders and the general public. The changes in this final rule were voted on and approved by the voting delegates at the 2014 NPIP National Plan Conference.

The establishments that will be affected by the rule—principally entities engaged in poultry production and processing—are predominantly small by Small Business Administration standards. In those instances in which an addition to or modification of requirements could potentially result in a cost to certain entities, we do not expect the costs to be significant. NPIP membership is voluntary. The changes contained in this final rule were decided upon by the NPIP General Conference Committee on behalf of Plan members; that is, the changes were recognized by the poultry industry as being in their interest.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR chapter IV.)

## Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform.

This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

## Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this final rule, which were filed under 0579-0445, have been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, if approval is denied, we will publish a document in the Federal Register providing notice of what action we plan to take.

## E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

## List of Subjects

### 9 CFR Part 56

Animal diseases, Indemnity payments, Low pathogenic avian influenza, Poultry.

9 CFR Parts 145, 146, and 147

Animal diseases, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR parts 56, 145, 146, and 147 as follows:

#### PART 56—CONTROL OF H5/H7 LOW PATHOGENIC AVIAN INFLUENZA

1. The authority citation for part 56 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

2. Section 56.1 is amended by revising the definition of breeding flock to read as follows:

##### § 56.1 Definitions.

\* \* \* \* \*

Breeding flock. A flock that is composed of stock that has been developed for commercial egg or meat production and is maintained for the principal purpose of producing progeny for the ultimate production of eggs or meat for human consumption.

\* \* \* \* \*

#### PART 145—NATIONAL POULTRY IMPROVEMENT PLAN FOR BREEDING POULTRY

3. The authority citation for part 145 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

##### § 145.2 [Amended]

4. In § 145.2, paragraph (d) is amended by removing the reference “§ 145.3(d)” and adding the reference “§ 145.3(e)” in its place.

5. Section 145.3 is amended as follows:



a. By redesignating paragraphs (a) through (f) as paragraphs (b) through (g), respectively.

b. By adding a new paragraph (a).

The addition reads as follows:

§ 145.3 Participation.

(a) The National Poultry Improvement Plan is a cooperative Federal-State-Industry program through which new or existing diagnostic technology can be effectively applied to improve poultry and poultry products by controlling or eliminating specific poultry diseases. The Plan consists of programs that identify States, flocks, hatcheries, dealers, and slaughter plants that meet specific disease control standards specified in the Plan. Participants shall maintain records to demonstrate that they adhere to the disease control programs in which they participate.

\* \* \* \* \*

§ 145.12 [Amended]

6. Section 145.12 is amended by adding, in paragraph (b), the words “made available to and” before the word “examined”.

7. Section 145.14 is amended as follows:

a. By revising paragraph (a)(5).

b. By revising paragraph (b)(1).

The revisions read as follows:

§ 145.14 Testing.

\* \* \* \* \*

(a) \* \* \*

(5) The official blood test shall include the testing of a sample of blood from each bird in the flock: Provided, That under specified conditions (see applicable provisions of §§ 145.23, 145.33, 145.43, 145.53, 145.63, 145.73, 145.83, and 145.93) the testing of a portion or sample of the birds may be used in lieu of testing each bird.

\* \* \* \* \*

(b) \* \* \*

(1) The official tests for M. gallisepticum, M. meleagridis, and M. synoviae shall be the serum plate agglutination test, the hemagglutination inhibition (HI) test, the enzyme-linked immunosorbent assay (ELISA) test<sup>3</sup>, or a molecular based test. The HI test or molecular based test shall be used to confirm the positive results of other serological screening tests. HI titers of 1:40 or more may be interpreted as suspicious, and final judgment must be based on further samplings and/or culture of reactors. Tests must be conducted in accordance with this paragraph (b) and in accordance with part 147 of this subchapter.

<sup>3</sup> Procedures for the enzyme-linked immunosorbent assay (ELISA) test are set forth in the following publications:

A.A. Ansari, R.F. Taylor, T.S. Chang, "Application of Enzyme-Linked Immunosorbent Assay for Detecting Antibody to Mycoplasma gallisepticum Infections in Poultry," Avian Diseases, Vol. 27, No. 1, pp. 21-35, January-March 1983; and

H.M. Opitz, J.B. Duplessis, and M.J. Cyr, "Indirect Micro-Enzyme-Linked Immunosorbent Assay for the Detection of Antibodies to Mycoplasma synoviae and M. gallisepticum," Avian Diseases, Vol. 27, No. 3, pp. 773-786, July-September 1983; and

H.B. Ortmayer and R. Yamamoto, "Mycoplasma Meleagridis Antibody Detection by Enzyme-Linked Immunosorbent Assay (ELISA)," Proceedings, 30th Western Poultry Disease Conference, pp. 63-66, March 1981.

\* \* \* \* \*

8. In § 145.42, paragraph (b) is revised to read as follows:

§ 145.42 Participation.

\* \* \* \* \*

(b) Hatching eggs should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.

\* \* \* \* \*

9. Section 145.53 is amended as follows:

- a. By revising paragraphs (c)(1)(i), (c)(1)(ii) introductory text, and (c)(1)(ii)(A).
- b. By revising paragraphs (d)(1)(i), (d)(1)(ii) introductory text, and (d)(1)(ii)(A).

The revisions read as follows:

§ 145.53 Terminology and classification; flocks and products.

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for M. gallisepticum as provided in §145.14(b) when more than 4 months of age or upon reaching sexual maturity: Provided, That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs from all the birds in the flock if the flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: And provided further, That a sample comprised of less than 30 birds may be tested at any one time, with the approval of the Official State Agency and the

concurrence of the Service, provided that a total of at least 30 birds, or all birds in the flock if flock size is less than 30, is tested within each 90-day period; or

(ii) It is a multiplier breeding flock which originated as U.S. M. Gallisepticum Clean baby poultry from primary breeding flocks and a random sample comprised of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock or all birds in the flock if the flock size is less than 30 birds, has been tested for M. gallisepticum as provided in §145.14(b) when more than 4 months of age or upon reaching sexual maturity: Provided, That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested; or

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(i) It is a flock in which all birds or a sample of at least 300 birds has been tested for M. synoviae as provided in §145.14(b) when more than 4 months of age or upon reaching sexual maturity: Provided, That to retain this classification, a random sample of serum or egg yolk or a targeted bird sample of the choanal palatine cleft/fissure area using appropriate swabs (C.P. swabs) from all the birds in the flock if flock size is less than 30, but at least 30 birds, shall be tested at intervals of not more than 90 days: And provided further, That a sample comprised of less than 30 birds may be tested at any one time with the approval of the Official State Agency

and the concurrence of the Service, provided that a total of at least 30 birds is tested within each 90-day period; or

(ii) It is a multiplier breeding flock that originated as U.S. M. Synoviae Clean chicks from primary breeding flocks and from which a random sample comprised of 50 percent of the birds in the flock, with a maximum of 200 birds and a minimum of 30 birds per flock or all birds in the flock if the flock is less than 30 birds, has been tested for M. synoviae as provided in §145.14(b) when more than 4 months of age or upon reaching sexual maturity: Provided, That to retain this classification, the flock shall be subjected to one of the following procedures:

(A) At intervals of not more than 90 days, a random sample of serum or egg yolk or a targeted bird sample of the choanal palantine cleft/fissure area using appropriate swabs from all the birds in the flock if the flock size is less than 30, but at least 30 birds shall be tested:

Provided, That a sample of fewer than 30 birds may be tested at any one time with the approval of the Official State Agency and the concurrence of the Service, provided that a total of at least 30 birds, or the entire flock if flock size is less than 30, is tested each time and a total of at least 30 birds is tested within each 90-day period; or

\* \* \* \* \*

10. Section 145.83 is amended as follows:

- a. By revising paragraph (f)(1)(i).
- b. By removing paragraphs (f)(1)(ii) and (f)(1)(iii).
- c. By redesignating paragraphs (f)(1)(iv) through (f)(1)(viii) as paragraphs (f)(1)(ii) through (f)(1)(vi).
- d. In newly redesignated paragraphs (f)(1)(v) and (f)(1)(vi) by removing the words “(f)(1)(vi)” and adding the words “(f)(1)(iv)” in their place.

e. By revising paragraph (f)(3).

The revisions read as follows:

§ 145.83 Terminology and classification; flocks and products.

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(i) Measures shall be implemented to control Salmonella challenge through feed, feed storage, and feed transport.

\* \* \* \* \*

(3) In order for a hatchery to sell products of paragraphs (f)(1)(i) through (f)(1)(vi) of this section, all products handled shall meet the requirements of the classification.

\* \* \* \* \*

11. In § 145.92, paragraph (b) is revised to read as follows:

§ 145.92 Participation.

\* \* \* \* \*

(b) Hatching eggs produced by primary and multiplier breeding flocks should be nest clean. They may be fumigated in accordance with part 147 of this subchapter or otherwise sanitized.

\* \* \* \* \*

§ 145.93 [Amended]

12. In § 145.93, paragraph (c)(3) is amended by removing the number "30" and adding the number "11" in its place.

PART 146–NATIONAL POULTRY IMPROVEMENT PLAN FOR COMMERCIAL  
POULTRY

13. The authority citation for part 146 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

14. Section 146.1 is amended by revising the definition of poultry to read as follows:

§ 146.1 Definitions.

\* \* \* \* \*

Poultry. Domesticated fowl, including chickens, turkeys, waterfowl, and game birds, except doves and pigeons, that are bred for the primary purpose of producing eggs or meat.

\* \* \* \* \*

15. Section 146.2 is amended by revising paragraph (c) to read as follows:

§ 146.2 Administration.

\* \* \* \* \*

(c)(1) An Official State Agency may accept for participation a commercial table-egg layer pullet flock, commercial table-egg layer flock, or a commercial meat-type flock (including an affiliated flock) located in another participating State under a mutual understanding and agreement, in writing, between the two Official State Agencies regarding conditions of participation and supervision.

(2) An Official State Agency may accept for participation a commercial table-egg layer pullet flock, commercial table-egg layer flock, or a commercial meat-type flock (including an affiliated flock) located in a State that does not participate in the Plan under a mutual understanding and agreement, in writing, between the owner of the flock and the Official State Agency regarding conditions of participation and supervision.

\* \* \* \* \*

§ 146.3 [Amended]

16. In § 146.3, paragraph (a) is amended by adding the words “commercial table-egg layer pullet flock,” before the words “table-egg producer”.

17. In § 146.11, paragraph (b) is revised to read as follows:

§ 146.11 Inspections.

\* \* \* \* \*

(b) A flock will be considered to be conforming to protocol if it meets the requirements as described in § 146.33(a), § 146.43(a), or § 146.53(a).

\* \* \* \* \*

§ 146.51 [Amended]

18. Section 146.51 is amended as follows:

a. In the definition of commercial upland game birds by removing the word “purpose” and adding in its place “purposes” and adding the words “eggs and/or” before the word “meat”.

b. In the definition of commercial waterfowl, by removing the word “purpose” and adding in its place “purposes” and adding the words “eggs and/or” before the word “meat”.

19. Section 146.52 is amended by revising paragraphs (a) and (c) to read as follows:

§ 146.52 Participation.

(a) Participating commercial upland game bird slaughter plants, commercial waterfowl slaughter plants, raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland game bird and commercial waterfowl producing eggs for human consumption premises shall comply with the applicable general provisions of subpart A of this part and the special provisions of this subpart E.



\* \* \* \* \*

(c) Raised-for-release upland game bird premises, raised-for-release waterfowl premises, and commercial upland game bird and commercial waterfowl producing eggs for human consumption premises that raise fewer than 25,000 birds annually are exempt from the special provisions of this subpart E.

20. Section 146.53 is amended as follows:

a. In paragraph (a) introductory text, by adding the words “or, in the case of egg-producing flocks, the regular surveillance of these flocks” after the words “participating slaughter plant”.

b. By adding paragraphs (a)(4) and (a)(5).

The additions read as follows:

§ 146.53 Terminology and classification; slaughter plants and premises.

\* \* \* \* \*

(a) \* \* \*

(4) It is a commercial upland game bird or waterfowl flock that produces eggs for human consumption where a minimum of 11 birds per flock have been tested negative to the H5/H7 subtypes of avian influenza as provided in § 146.13(b) within 30 days of disposal or within a 12 month period.

(5) It is a commercial upland game bird or waterfowl flock that has an on-going active and passive surveillance program for H5/H7 subtypes of avian influenza that is approved by the Official State Agency and the Service.

\* \* \* \* \*

## PART 147–AUXILIARY PROVISIONS ON NATIONAL POULTRY IMPROVEMENT PLAN

21. The authority citation for part 147 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

22. In § 147.52, paragraph (d) is revised to read as follows:

§ 147.52 Authorized laboratories.

\* \* \* \* \*

(d) State site visit. The Official State Agency will conduct a site visit and recordkeeping audit at least once every 2 years. This will include, but may not be limited to, review of technician training records, check test proficiency, and test results. The information from the site visit and recordkeeping audit will be made available to the NPIP upon request.

\* \* \* \* \*

23. Section 147.54 is revised to read as follows:

§147.54 Approval of diagnostic test kits not licensed by the Service.

(a) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) may be approved through the following procedure:

(1) The sensitivity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known positive samples, as determined by the official NPIP procedures found in the NPIP Program Standards or through other procedures approved by the Administrator. Field samples for which the presence or absence of the target organism or analyte has been determined by the current NPIP test should be used, not spiked samples or pure cultures. Samples from a variety of field cases representing a range of low, medium, and high analyte concentrations should be used. In some cases it may be necessary to utilize samples from experimentally infected animals. Spiked samples (clinical sample matrix with a known

amount of pure culture added) should only be used in the event that no other sample types are available. Pure cultures should never be used. Additionally, laboratories should be selected for their experience with testing for the target organism or analyte with the current NPIP approved test. If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(2) The specificity of the kit will be evaluated in at least three NPIP authorized laboratories by testing known negative samples, as determined by tests conducted in accordance with the NPIP Program Standards or other procedures approved by the Administrator in accordance with §147.53(d)(1). If certain conditions or interfering substances are known to affect the performance of the kit, appropriate samples will be included so that the magnitude and significance of the effect(s) can be evaluated.

(3) The kit will be provided to the cooperating laboratories in its final form and include the instructions for use. The cooperating laboratories must perform the assay exactly as stated in the supplied instructions. Each laboratory must test a panel of at least 25 known positive samples. In addition, each laboratory will be asked to test at least 50 known negative samples obtained from several sources, to provide a representative sampling of the general population. The cooperating laboratories must perform a current NPIP procedure or NPIP approved test on the samples alongside the test kit for comparison.

(4) Cooperating laboratories will submit to the kit manufacturer all raw data regarding the assay response. Each sample tested will be reported as positive or negative, and the official NPIP procedure used to classify the sample must be submitted in addition to the assay response value. A completed worksheet for diagnostic test evaluation is required to be submitted with the

raw data and may be obtained by contacting the NPIP Senior Coordinator. Raw data and the completed worksheet for diagnostic test evaluation must be submitted to the NPIP Senior Coordinator 4 months prior to the next scheduled General Conference Committee meeting, which is when approval will be sought.

(5) The findings of the cooperating laboratories will be evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to approve the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends approval, the final approval will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

(6) Diagnostic test kits that are not licensed by the Service (e.g., bacteriological culturing kits) and that have been approved for use in the NPIP in accordance with this section are listed in the NPIP Program Standards.

(b) Approved tests modification and removal. (1) The specific data required for modifications of previously approved tests will be taken on a case-by-case basis by the technical committee.

(2) If the Technical Committee determines that only additional field data is needed at the time of submission for a modification of a previously approved test, allow for a conditional approval for 60 days for data collection side-by-side with a current test. The submitting party must provide complete protocol and study design, including criteria for pass/fail to the Technical Committee. The Technical Committee must review the data prior to final approval. This would only apply to the specific situation where a modified test needs additional field data with poultry to be approved.

(3) Approved diagnostic tests may be removed from the Plan by submission of a proposed change from a participant, Official State Agency, the Department, or other interested person or industry organization. The data in support of removing an approved test will be compiled and evaluated by the NPIP Technical Committee, and the Technical Committee will make a majority recommendation whether to remove the test kit to the General Conference Committee at the next scheduled General Conference Committee meeting. If the Technical Committee recommends removal, the final decision to remove the test will be granted in accordance with the procedures described in §§ 147.46, 147.47, and 147.48.

Done in Washington, DC, this 9<sup>th</sup> day of August 2016.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.  
[FR Doc. 2016-19245 Filed: 8/11/2016 8:45 am; Publication Date: 8/12/2016]